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Charles P. Landrum

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
David N. Herdon *et al.*

Serial No.: 10/025,274

Filed: December 13, 2002

For: METHODS TO ENHANCE WOUND HEALING AND ENHANCED WOUND COVERAGE MATERIAL

Group Art Unit: 1632

Examiner: Maria B. Marvich

Atty. Dkt. No.: CLFR:184USD1

DECLARATION OF DAVID N. HERNDON, M.D. UNDER 37 C.F.R. §1.132

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

I, Marc G Jeschke, MD, PhD, MMS, do declare that:

1. I am familiar with the subject matter disclosed and claimed in the above referenced patent application. I am a recognized expert in the field of surgery and in particular wound healing as evidenced by the following:

- I am an Assistant Professor in the department of Surgery at the University of Texas Medical Branch.
- I am the Assistant Director of Research at Shriners Hospital for Children.
- I have published over 100 articles in peer-reviewed journals and authored over 10 book chapters concerning surgical and pharmaceutical approaches for wound trauma therapy.

- I have trained over 25 researchers and medical doctors in the field.
- A copy of my *curriculum vitae* which verifies the foregoing is attached as Exhibit A.

2. Studies in the instant application demonstrate the efficacy of cationic/cholesterol liposomes for treating wound trauma. Surprisingly, local treatment of wounds with these liposomes resulted in systemic benefits in the animals. This result would not have been predicted in view of the knowledge in the art at the time the invention was made.

3. A major complication associated with burn wounds is the hypermetabolic response that follows the burn trauma. This systemic response causes patient to experience weight loss and loss of muscle mass that complicate treatment and correspond to poor clinical outcome. The instant invention provides methods for treating external wounds and hypermetabolic response with cholesterol containing cationic liposomes.

4. Hypermetabolic response results in weight loss in subjects suffering from burn wound trauma. Interestingly, as shown in the instant application, animals receiving injections of cationic/cholesterol liposomes showed a delay in weight lose after burn trauma. As illustrated in Figure 5, treated animals exhibited significantly less change in body weight at 3, 4, and 5 days after receiving a burn. In fact, treated animals maintained a positive change (increase) in body weight until six days after the burn trauma, while untreated animals began to lose weight on day three.

5. One serum marker for hypermetabolic response is a decrease in total serum protein concentrations. Interestingly, studies presented in Example 7 (on page 38) of the instant application demonstrate that cationic, cholesterol containing liposomes were able to raise serum

protein levels in treated animals as compared to the control animals. These data indicate an attenuation of the hypermetabolic response by the liposomes.

6. Another hallmark of hypermetabolic response is a decrease in serum trasferrin levels. Interestingly, administration of cationic/cholesterol liposomes also had a positive impact on serum transferrin levels. Figure 6 of the application shows the characteristic decrease in serum transferrin levels following burn trauma can be partially attenuated by the administration of cholesterol containing cationic liposomes.

7. Another aspect of the hypermetabolic response is elevation of type I acute phase proteins in the serum of effected animals. One acute phase protein that is often tracked as a marker of hypermetabolic response is α_1-acid glycoprotein. As shown in Figure 7 of the application, cholesterol containing cationic liposomes were able to significantly decrease the serum levels α_1-acid glycoprotein at 1 and 5 days following burn trauma. Again, these data demonstrate that the liposome compositions were effective in reducing the systemic hypermetabolic response.

8. Still another marker of hypermetabolic response is an increase in the level of serum proinflammatory cytokines, such as interleukin 1β (IL-1β) and tumor necrosis factor-α (TNF-α). Cholesterol containing cationic liposomes were also able to lower serum levels of these proinflammatory cytokines. As shown in Figures 8 and 9 of the application, serum IL-1β and TNF-α were both decreased in animals treated with these liposomes as compared to control animals.

9. Taken together the studies presented in the application show that cationic liposomes containing cholesterol have the surprising property of attenuating the hypermetabolic

response in animals with external wound trauma. The liposomes alone demonstrate this therapeutic benefit and thus are an ideal vector for the delivery of further therapeutics to external wounds such as growth factors.

8. The foregoing systemic effects of cationic/cholesterol liposomes on hypermetabolic response would not have been predictable based on the knowledge in the art at the time this invention was made.

9. None of the references cited by the Examiner teach the use of the cationic/cholesterol containing liposomes to treat a hypermetabolic response.

10. I understand the Examiner has asserted that U.S. Patent No. 6,120,799 to McDonald and a paper by Yang (Yang *et al., Neuroreport,* 8:2355-2358, 1997) teach the use of cationic liposomes with cholesterol in gene delivery. However, neither of these references teach or suggest that such liposomes would have the surprising and unexpected therapeutic benefits that have been described in the instant application.

11. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

11/20/06

Date

Marc G Jeschke, MD, PhD, MMS

Exhibit A

CURRICULUM VITAE

Name Marc G Jeschke, MD PhD, MMS.

Current position
Assistant Professor
Assistant Director of Research and Staff Surgeon
Shriners Hospital for Children and
Department of Surgery
Department of Biochemistry & Molecular Biology
University Texas Medical Branch, Galveston, Texas.

Address
work: 815 Market Street
Galveston, Texas 77550

private: 1124 Shady Knoll Lane
League City, Texas, 77573

Biographical Data

Date of Birth:	2 January 1968
Place of Birth:	Bochum, Germany
Citizenship:	German, Green Card Holder
Marital Status:	married, 4 children

Education

1974-1978	Eduard-Spranger Elementary School, Freudenstadt.
1978-1987	Kepler-Gymnasium, High school, Freudenstadt, Germany. Degree: Abitur (High School Diploma).
1988-1994	Medical School, Eberhard-Karls-University, Tübingen, Germany. Degree: Medical Doctor.
1990-1993	Head of the surgical scientific group: minimal invasive surgery, Department of Surgery, University of Tübingen, Germany.
1991	Elective in surgery, Department of surgery, Baden-Baden, Germany.
1992	Elective in surgery, Department of surgery, University of Tübingen, Germany.
1992	Elective internal medicine, Reutlingen, Germany.
1992	Elective in surgery, Freudenstadt, Germany.
4/1998-8/1999	Master of Medical Science Degree, Graduate School of Biomedical Science, University of Texas Medical Branch, United States of America.
3/2001-3/2002	Habilitation (PhD) experimental surgery: "The effect of growth factors on the hepatic acute phase response and signal transduction after thermal injury".
4/2005	USMLE Step 1

Residency

1/1995-7/1996	Internship and PGY-2, Marienhospital, Department of Surgery, Gynecology and Obstetrics, Stuttgart, Germany.
7/1996-5/1999	Fellow, Shriners Hospital for Children and University of Texas Medical Branch, Department of Surgery.
5/1999-6/2003	PGY-2-5, Surgical Resident, Klinik und Poliklinik für Chirurgie, University of Regensburg, Germany.
8/2000-6/2003	Head of the wound healing outpatient clinic, University of Regensburg, Germany.
7/2003-6/2004	Staff surgeon, Department of Plastic and Hand Surgery, University of Erlangen, Germany.
10/2003	Boards General Surgery.
9/2005-6/2006	Clinical Fellowship, Shriners Hospital for Children, Galveston Burn Unit.
7/2006-present	Attending Burn Surgeon, Shriners Hospital for Children, and Blocker Burn Unit, UTMB, Gaveston.

Military Service

1987-1988	Army, Wildermuth-Kaserne, Böblingen, Germany.

Professional Experience

1990-1995	Dissertation (MD): Determination of the healing mechanisms of small vascular polyurethane prosthesis. Graduation: summa cum laude.
7/1996-12/96	Fellowship Shriners Burns Institute, Galveston and University of Texas Medical Branch.
1/1997-5/1999	Clayton Foundation Research Fellowship, Clayton Foundation and Shriners Burns Institute and Department of Surgery, University of Texas Medical Branch, Galveston, Texas.
7/1998-5/1999	Research Associate, Shriners Hospital for Children, Galveston, Texas.
5/1999-6/2003	Laboratory chief, Department of Surgery, University of Regensburg.
7/2003-6/2004	Laboratory chief, Department of Plastic and Hand Surgery, University of Erlangen.
7/2004-present	Assistant Professor and Assistant Director of Research, Shriners Hospital for Children and University of Texas Medical Branch, Department of Surgery, Galveston, Texas.
8/2005-present	Faculty Temporary License No 40790, Texas State Board of Medical Examiners.

Research Activities

Principal Investigator:

1999-2000	ReFOrM, Antrag auf Fördermittel im Rahmen der Regensburger Forschungsförderung in der Medizin. Non-viral gene therapy to improve wound healing.
2001-2004	German Research Counsil (Deutsche Forschungsgemeinschaft DFG; JE 233/2-1). Non-virale Gen-Therapie zur Verbesserung der dermalen Regeneration.
2001-2004	MBT Biotech: Definition of an endothelial specific liposomal complex for gene transfer.
2001-2003	Johnson & Johnson. The effect of „Promogran" on wound healing mechanisms.
2003-2005	German Research Counsil (Deutsche Forschungsgemeinschaft DFG; JE 233/6-1). Identification of the hepatic insulin and catecholamine signalling pathway after major trauma.
2006-2008	American Surgical Association. The effect of insulin on the hepatic PI3K/Akt/Wnt/Foxo pathway during stress.

Co-Investigator:

1999-2009	Medical Technologies and Product Development for Burns, Trauma and Wound healing. Fetal Membrane as a new wound coverage material. Clayton Foundation for Research.
2004-2009	Assessment of Mechanisms of improved wound healing and protein metabolism of insulin in severely burned patients. Shriners Grant SHG 8660.
2004-2010	Gene therapy as a new therapeutic strategy to improve wound healing. Carl C. Sr. and Marie Jo Anderson Charitable Foundation.
2004-2006	Modulation of the Postburn Hypermetabolic Response, NIH 1 R01-GM56687.
2004-2009	Safety and Efficacy of Treatment of Major Pediatric Burns with Oxandrolone and/or Resistive Cardiovascular Exercise During the First Year Post Discharge, Shriners Hospitals for Children SHG 8760.
2005-2010	Burn Center Grant: Assessment of Anabolic Agents/Exercise in burn children. NIH P50 GM60338.
2006-2011	Training Grant: Postdoctoral Training in Trauma and Burns. NIH T32 GM08256

Honors

1996	Clayton Foundation Fellowship Appointee.
1997	American College of Surgeons Committee on Trauma, South Texas Chapter, Winner Residents Award.
1998	Selected for presentation American College of Surgeons Residents Competition, South Texas Chapter.
1998	Young Investigator Travel Award, International Symposium on Regulatory Peptides, Mackinac Island, MI, USA.
1998	American College of Surgeons Committee on Trauma, South Texas Chapter, Winner Residents Award.
1999	Selected for presentation American College of Surgeons Residents Competition, South Texas Chapter.

1998	American College of Surgeons Committee on Trauma, Region VI. Winner Residents Award and selected for presentation at the National Competition, Washington DC.
1998	Johann-Nepomuk-von-Nussbaum Prize der Bayerischen Gesellschaft für Chirurgie.
2001	Otto-Götze Prize of the Bavarian Society of Surgery.
2001	Selected for presentation of the Heinz-Kalk memorial award.
2001	Wound healing-Prize, German College of Surgeons.
2002	Best scientific presentation at the 1st World meeting of the Surgical Infection Society, Madrid, Spain.
2002	Dr. Werner Fekl Förderprize of the German Society of Critical Care Medicine.
2003	Prize fort the best scientific work from the German College of Surgeons, Critical care Chapter.
2004	Von-Langenbeck-Prize from the German College of Surgeons.
2005	Surgery Specialty Award, Society Critical Care Medicine.
2005	First Prize Poster Presentation, American Burn Association.
2006	Faculty/Fellow Award of the Amercian Surgical Association.

Membership in Scientific Societies and Organizations (elected)

1997	American Burn Association.
1998	Association for Academic Surgery.
2001	Deutsche Gesellschaft für Chirurgie (German College of Surgery).
2001	European Shock Society.
2002	German College of Surgery. Chapter Wound healing.
2002	German College of Surgery. Chapter Surgical Research.
2003	European Tissue and Repair Society.
2004	Shock Society
2004	International Society of Burn Injuries
2005	Surgical Infection Society
2005	Society for Critical Care Medicine
2006	The American Association for the Surgery of Trauma

Fellows, doctoral and post-doctoral students

1999-2004 Dieter Weck (MD)
2000-2003 Christian Heilmeyer (MD)
2001-2003 Doerte Vormann (MD)
2000-2004 Michael Hartl (MD)
2000-2004 Mathias Aust (MD)
2000-2004 Tim Steffens (MD)
2001-2007 Ulla Müller (MD)
2001-2004 Dagmar Klein (PhD)
2001-2004 Thomas Seubert (MD)
2002-2005 Andreas Meis (MD)
2003-2004 Anke Jäckel (MD)
2003-2005 Harry Steinherr (MD)
2004-2006 Mareike Krickhahn (MD)
2004-2005 Christian Ibold (MD)
2004-2005 Enrico Wolf (MD)
2004-2006 Rene Przkora (MD)
2004-2006 Celeste Finnerty, (PhD)
2005-dato Joerg Jaekel (MD)
2005-dato Markus Bolle (MD)
2005-dato Andreas Meierhoefer (MD)
2004-dato Ludwig Branski (MD)
2005-dato Will Norbury (MD)
2005-dato Andrea Obenauf (MD)
2005-dato Yvonne Raddatz (MD)

2006-dato Jackie Song (MD)
2006-dato Anna Mlynarczyk (MD)
2006-dato Gerd Gauglitz (MD)

Languages spoken

German, English, French.

Articles published in Journals (peer reviewed)

1. **Jeschke M**, Hermanutz V, Frick E, Fingerle J, Köveker G. Comparison of small vascular prosthesis of Polytetrafluorethylene (PTFE) and Polyurethane (PU). Helv. Chir. Acta. 1993; 59: 881-886.
2. Bschorer R, Köveker G, Gehrke G, **Jeschke M**, Hermanutz V. Experimental improvement of microvascular allografts with the new material polyurethane and microvessel endothelial cell seeding. Int. J. Oral Maxillofac. Surg. 1994; 23: 389-392.
3. Jarrar D, Wolf SE, **Jeschke MG**, Ramirez RJ, DebRoy M, Ogle C, Papaconstantinou J, Herndon DN. Growth Hormone treatment effectively attenuates the acute phase response to thermal injury. Arch. Surg 1997; 132: 1171-1176.
4. Wolf SE, **Jeschke MG**, Desai MH, Rose JK, Chinkes DL, Herndon DN. Enteral feeding intolerance as an early indicator of sepsis associated with mortality in massively burned children. Arch. Surg 1997; 132: 1310-1314.
5. **Jeschke MG**, Herndon DN. Inhalation injury. Crit Care Med. 1998; S98: 211-213.
6. **Jeschke MG**, Barrow RE, Wolf SE, Herndon DN. Mortality in burned children with acute renal failure. Arch. Surg 1998; 134: 752-756.
7. **Jeschke MG**, Wolf SE, DebRoy MA, Jarrar D, Herndon DN. Recombinant human growth hormone (rhGH) down regulates hepatocyte growth factor (HGF) in burns. J Surg Res 1998; 76: 11-16.
8. Chrysopoulo MT, **Jeschke MG**, Dziewulski P, Barrow RE, Herndon DN. Acute renal failure in burns. J Trauma 1999; 46: 141-144.
9. **Jeschke MG**, Hermanutz V, Wolf SE, Köveker GB. Polyurethane vascular prostheses decreases neointimal formation compared to expanded polytetrafluorethylene. J Vasc Surg 1999; 29: 168-176.
10. Chrysopoulo MT, **Jeschke MG**, Ramirez RJ, Barrow RE, Herndon DN. Growth hormone attenuates TNF-α in burned children. Arch. Surg 1999; 134: 283-286.
11. Mittendorfer B, **Jeschke MG**, Wolf SE, Sidossis LS. Nutritional hepatic steatosis and mortality after burn injury in rats. Clin Nutr 1998; 17(6): 293-299.
12. **Jeschke MG**, Herndon DN, Wolf SE, DebRoy MA, Rai **J**, Lichtenbelt BJ, Barrow RE. Recombinant human growth hormone alters acute phase reactant proteins, cytokine expression and liver morphology in burned rats. **J** Surg Res 1999; 83 (2): 122-129.
13. Rai J, **Jeschke MG**, Barrow RE, Herndon DN. Electrical injuries: A 30 year review. J Trauma 1999; 46 (5): 933-936.
14. **Jeschke MG**, Barrow RE, Hawkins HK, Yang K, Hayes R, Lichtenbelt BJ, Perez-Polo JR, Herndon DN. IGF-I gene transfer in thermal trauma. Gene Therapy 1999; 6 (6): 1015-1020.
15. **Jeschke MG**, Chrysopoulo MT, Herndon DN, Wolf SE. Increased expression of insulin-like growth factor-I in serum and liver with recombinant human growth hormone treatment in thermally injured rats. **J** Surg Res 1999; 85 (1): 171-177.
16. Barret JP, Dziewulski P, **Jeschke MG**, Wolf SE, Herndon DN. Effects of recombinant human growth hormone on burn scar development. Plast Recons Surg 1999; 104: 726-729.

17. **Jeschke MG**, Wolf SE, DebRoy MA, Herndon DN. The combination of growth hormone with hepatocyte growth factor alters the acute phase response. Shock 1999; 12 (3): 181-187.
18. **Jeschke MG**, Wolf SE, DebRoy MA, Thompson JC. The effect of growth hormone, hepatocyte growth factor, and insulin-like growth factor-I administration on gut mucosal proliferation and apoptosis after thermal injury. Surg Forum 1999; 85: 62-64.
19. Chappell VL, Wolf SE, Thompson MD, **Jeschke MG**, Chung DH, Thompson JC. Effects of incremental starvation on gut mucosa. Surg Forum 1999; 85: 58-60.
20. **Jeschke MG**, Barrow RE, Perez-Polo JR, Herndon DN. Cholesterol-containing cationic liposomes attenuate type I acute phase proteins and pro-inflammatory cytokines in thermally injured rats. Arch Surg 1999; 134: 1098-1102.
21. **Jeschke MG**, Barrow RE, Hawkins HK, Chrysopoulo MT, Perez-Polo JR, Herndon DN. Impact of multiple injections of an IGF-I gene construct after thermal injury. Arch Surg 1999; 134: 1137-1141.
22. **Jeschke MG**, Barrow RE, Herndon DN. IGF-I/IGFBP-3 attenuates the pro-inflammatory acute phase response in severely burned children. Ann Surg 2000; 231 (2): 246-252.
23. **Jeschke MG**. Non-viral gene therapy to improve wound healing. European Tissue Repair Society Bulletin 1999; 6 (4): 113-115.
24. **Jeschke MG**, Barrow RE, Hawkins HK, Tao Z, Perez-Polo JR, Herndon DN. Biodistribution and feasibility of non-viral IGF-I gene transfers in thermally injured skin. Lab Invest 2000; 80 (2): 151-158.
25. **Jeschke MG**, Herndon DN, Wolf SE, DebRoy MA, Rai J, Thompson JC, Barrow RE. Hepatocyte growth factor (HGF) modulates the hepatic acute phase response in thermally injured rats. Critical Care Med 2000; 28: 504-510.
26. **Jeschke MG**, Herndon DN, Barrow RE. Long term outcomes of burned children after in-hospital cardiac arrest. Crit Care Med 2000; 28: 517-520.
27. Barrow RE, **Jeschke MG**, Herndon DN. Early release of third-degree eyelid burns prevents eye-injury. Plast Recons Surg 2000; 105: 860-864.
28. **Jeschke MG**, Herndon DN, Barrow RE. Insulin-like growth factor-I plus insulin-like growth factor binding protein-3 affects the hepatic acute phase response and hepatic morphology in thermally injured rats. Ann Surg 2000; 231 (3): 408-416.
29. **Jeschke MG**, DebRoy MA, Wolf SE, Rajaraman S, Thompson JC. Burn and starvation increase programmed cell death in small bowel epithelial cells. Diges Dis Sci 2000; 45 (2): 415-420.
30. **Jeschke MG**, Barrow RE, Herndon DN. Recombinant human Growth Hormone (rhGH) treatment in pediatric burn patients and its role during the acute phase response. Crit Care Med 2000; 28: 1578-1584.
31. Wolf SE, DebRoy MA, Ikeda H, **Jeschke M**, Matin S, Rajaraman S, Ko TC, Englander EW, Norman JG, Thompson JC. Increased small bowel epithelial turnover in interleukin-1 receptor knockout mice. Ann Surg 2000; 232: 42-45.
32. Barrow RE, **Jeschke MG**, Herndon DN. Early fluid resuscitation improves outcomes in thermally injured children. Resuscitation 2000; 45: 91-96.
33. Yamashita Y, **Jeschke MG**, Wolf SE. Differential expression of hepatocyte growth factor in liver, kidney, lung and spleen following burn in rats. Cytokine 2000; 12: 1293-1298.
34. Volpi E, **Jeschke MG**, Herndon DN, Wolfe RR. Measurement of skin protein breakdown in a rat model. Am J Physiol 2000; 279: E900-907.
35. Baer W, **Jeschke MG**, Ruf S. Der schwierige Dekubitus. J Wound Healing 2000; 16: 6-8.
36. **Jeschke MG**, Low JFA, Spies M, Vita R, Hawkins H, Herndon DN, Barrow RE. Cell proliferation, apoptosis, NF-κB expression, enzyme, protein, and weight changes in livers of burned rats. Am J Physiol 2001; 280: G1314-G1320.
37. **Jeschke MG**, Richter W, Ruf SG. Cultured autologous outer root sheath cells: a new therapeutic alternative for chronic decubital ulcers. Plastic Recons Surg 2001; 107: 1803-1806.

38. Low JF, Barrow RE, Mittendorfer B, **Jeschke MG**, Chinkes D, Herndon DN. The effect of short-term growth hormone treatment on growth and energy expenditure in burned children. Burns 2001; 27: 447-453.
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40. Varedi M, **Jeschke MG**, Englander E, Herndon DN, Barrow RE. Serum TGF-β in thermally injured rats. Shock 2001; 16: 380-382.
41. Barrow RE, Meyer NA, **Jeschke MG**. Effect of varying burn sizes and ambient temperatures on the hypermetabolic rate in thermally injured rats. J Surg Res 2001; 99: 253-257.
42. Barret JP, **Jeschke MG**, Herndon DN. Fatty infiltration of the liver in paediatric burn patients: Autopsy findings and clinical implications. J Trauma 2001; 51 (4): 736-739.
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44. **Jeschke MG**, Herndon DN, Baer W, Barrow RE, Jauch KW. Possibilities of Gen Transfer to improve dermal and epidermal regeneration. Current Gene Therapy 2001; 1: 267-278.
45. **Jeschke MG**, Herndon DN, Ebener C, Baer W, Jauch KW. A high vitamin, protein and amino acid nutrition improves protein metabolism during the hypermetabolic state after a burn injury. Arch Surg 2001; 136: 1301-1306.
46. **Jeschke MG**, Richter G, Geissler EK, Perez-Polo JR, Herndon DN, Hofstätter F, Jauch KW. Therapeutic success and efficacy of non-viral liposomal cDNA gene transfer to the skin is dose dependent. Gene Therapy 2001; 8: 1777-1784.
47. Chrysopoulo MT, McGrouther DA, **Jeschke MG**, Kaufman BR. Cleland's Ligaments: an anatomic study. Plast Recons Surg 2002; 109: 566-575.
48. Spies M, Wolf SE, Barrow RE, **Jeschke MG**, Herndon DN. Modulation of Type I and II Acute Phase Reactants with Insulin-like Growth Factor-1/Binding Protein-3 Complex in Severely Burned Children. Crit Care Med 2002, 30 (1): 83-88.
49. **Jeschke MG**, Richter G, Hofstätter F, Perez-Polo JR, Herndon DN, Jauch KW. Non-viral, liposomal Keratinocyte Growth Factor (KGF) cDNA Gene Transfer improves dermal and epidermal regeneration through stimulation of epithelial and mesenchymal factors. Gene Therapy 2002; 9 (16): 1065-1074.
50. **Jeschke MG**, Barrow RE, Suzuki F, Herndon DN. IGF-I/IGFBP-3 equilibrates ratios of pro- to anti-inflammatory cytokines which are predictors for organ function in severely burned pediatric patients. Mol Med 2002; 8(5): 238-246.
51. **Jeschke MG**, Einspanier R, Klein D, Jauch KW. Insulin attenuates the systemic inflammatory response to thermal trauma. Mol Med 2002; 8(8): 443-450.
52. Chappell VL, Thompson MD, **Jeschke MG**, Chung DH, Thompson JC, Wolf SE. Effects of incremental starvation on gut mucosa. Dig Dis Sci 2003; 48(4): 765-769.
53. **Jeschke MG**, Horch RE. Kombinierte Behandlung aus einer Kollagenmatrix, Fibrinkleber und Vakuum-Verbänden. Plastische Chirurgie 2003; 3: 127-131.
54. Loos B, **Jeschke MG**, Kopp J, Lang W, Horch RE. Modern plastic surgical concepts to reconstruct chronic wounds. Journal for Wound Healing 2003, 5: 185-193.
55. Ramzy PI, **Jeschke MG**, Wolf SE, Swischuk L, Heggers JP, Herndon DN. Correlation of Bronchoalveolar Lavage with Radiographic Evidence of Pneumonia in Thermally Injured Children. Journal Burn Care Rehab 2003; 24(6): 382-385.
56. Klein D, Einspanier R, Bolder U, **Jeschke MG**. Differences in signal transcription pathway and cytokine expression between thermal injury and sepsis. Shock 2003; 20(6): 536-543.
57. **Jeschke MG**. Intensivierte Insulintherapie bei Sepsis-Verbesserung der Überlebenschancen? Der Anaesthesist 2003; 52: S20-23.
58. **Jeschke MG**. Gentherapie - ein neuer therapeutischer Ansatz zur Behandlung des diabetischen Fussulkus. Gene therapy - a new therapeutic approach to the treatment of diabetic foot ulcer. Langenbeck Arch Chir Suppl 2 2003:156-9.

59. **Jeschke MG**, Rose C, Füchtmeier B, Angele P, Nerlich MN, Bolder U. Development of new reconstructive techniques: the use of Integra in combination with fibrin glue and negative pressure therapy for reconstruction of acute and chronic wounds. Plast Recons Surg 2004; 113: 525-530.
60. **Jeschke MG**, Klein D. Gene transfer of multiple genes is more effective then gene transfer of a single gene. Gene Therapy 2004; 11(10): 847-55.
61. Altmeppen J, Hansen E, Bonnländer GL, Horch RE, **Jeschke MG**. Composition and characteristics of an autologous thrombocyte gel. J Surg Res 2004; 117: 202-207.
62. **Jeschke MG**, Klein D, Herndon DN. Insulin treatment improves the systemic inflammatory reaction and hepatic acute-phase-response to severe thermal injury. Ann Surg 2004; 239(4): 553-560.
63. **Jeschke MG**, Schubert T, Klein D. Exogenous liposomal IGF-I cDNA gene transfer leads to endogenous cellular and physiological responses in an acute wound. Am J Physiol Regul Integr Comp Physiol. 2004; 286(5): R958-66.
64. Kopp J, Bach AD, Kneser U, Polykandriotis E, Loos B, Krickhahn M, **Jeschke MG**, Horch RE. Indication and clinical results of buried skin grafting to treat problematic wounds. Zentralbl Chir. 2004; 129 Suppl 1: 129-32.
65. Klein D, Schubert T, Horch RE, Jauch KW, **Jeschke MG**. Insulin treatment improves hepatic morphology and function after severe trauma. Ann Surg 2004; 240: 340-349.
66. **Jeschke MG**, Barrow RE, Herndon DN. Long-term persistence of the hepatic acute phase response in severely burned pediatric patients. Arch Surg 2004; Jun; 139 (6): 641-647.
67. **Jeschke MG,** Herndon DN. Effect on growth factors as therapeutic drugs on hepatic metabolism during the systemic inflammatory response syndrome. Cur Drug Metabolism 2004; 5: 399-413.
68. **Jeschke MG**, Klein D, Bolder U, Einspanier R. Insulin attenuates the systemic inflammatory response in endotoxemic rats. Endocrinology 2004, 145 (9): 4084-4093.
69. **Jeschke MG**. Mechanisms and possibilities of liposomal Gene transfer to affect dermal and epidermal regeneration using the IGF-I cDNA construct. Gene Therapy and Molecular Biology 2004; 8: 201-212.
70. Kopp J, **Jeschke MG**, Bach AD, Kneser U, Horch RE. Applied tissue engineering in the closure of severe burns and chronic wounds using cultured human autologous keratinocytes in a natural fibrin matrix. Cell and Tissue Bank 2004; 5(2): 81-7.
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72. **Jeschke MG**, Barrow RE, Mlcak RP, Herndon DN. Endogenous anabolic hormones, effects of trauma and gender. Ann Surg 2005; May; 241(5): 759-768.
73. Golder S, **Jeschke M**, Jauch K, Scholmerich J, Messmann H. Traumatic incomplete rupture of the gastric wall: endoscopic treatment with clip application. Endoscopy. 2005 May; 37(5): 497-498.
74. **Jeschke MG**, Sandmann G, Schubert Th, Klein D. Effect of oxidized regenerated cellulose/collagen matrix on dermal and epidermal healing and growth factors in an acute wound. Wound Repair Regen. 2005 May-Jun;13(3):324-31.
75. **Jeschke MG**, Klein D, Rensing H, Bolder U, Croner R. Insulin prevents liver damage and preserves liver function during endotoxemia. J Hepatology 2005 Jun; 42(6): 870-879. Epub 2005 Feb 22.
76. **Jeschke MG**, Schubert T, Krickhahn M, Polykandriotis E, Klein D, Perez-Polo JR, Przkora R, Herndon DN. Interaction of exogenous liposomal insulin-like growth factor-I cDNA gene transfer with growth factors on collagen expression in acute wounds. Wound Repair Regen. 2005 May-Jun;13(3):269-77.
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97. Pereira CT, Maamar-Tayeb M, Burke A, Perez-Polo JR, Herndon DN, **Jeschke MG**. Immunohistochemical staining of transgenic beta-galactosidase in burned skin is a better

indicator of transfection efficiency than histochemical techniques. J Immunol Methods. 2006 Aug 2; [Epub ahead of print].
98. **Jeschke MG**, Bolder U, Herndon DN, Przkora R, CC Finnerty, Thompson JC, Wolf SE. The effect of insulin-like growth factor-I administration on gut mucosal homeostasis and cellular mediator after thermal injury. Endocrinology 2006; [Epub ahead of print].
99. Baregamian N, Song J, **Jeschke MG**, Evers BM, Chung DH. IGF-I protects intestinal epithelial cells from oxidative stress-induced apoptosis. J Surg Res 2006 [Epub ahead of print].
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104. Przkora R, Haslbeck M, **Jeschke MG**, Herndon DN, Bolder U. Heat Stress Modulates Hepatocyte Membrane Proteins During Endotoxemia. Burns 2006 (in press).
105. Pereira CT, Herndon DN, Rocker R, **Jeschke MG**. Liposomal KGFcDNA gene transfer enhances dermal and epidermal regeneration by stimulating collagen IV and mesenchymal and epithelial growth factors. J Surg Res 2006 (in press).
106. **Jeschke MG**, Chinkes DL, Finnerty CC, Przkora R, Pereira CT, Herndon DN. Blood transfusions are associated with increased risk for the development of sepsis in severely burned pediatric patients. Crit Care Med 2006 (in press).
107. **Jeschke MG**, Herndon DN. The combination of IGF-I and KGF cDNA improves dermal and epidermal regeneration by increased neovascularization. Gene Therapy 2006 (in review).
108. **Jeschke MG**, Mlcak RP, Herndon. DN Morphologic changes of the liver after a severe thermal injury. Shock 2006 (in review).
109. Leffler M, Hrach T, Stuerzl M, Horch RE, **Jeschke MG**. Insulin inhibits apoptosis and exerts anti-inflammatory effects in human macrophages stimulated with LPS. Shock 2006 (in review).
110. **Jeschke MG**, Norbury W, Finnerty CC, Przkora R, Branski LK, Herndon DN. Propranolol does not increase inflammation, sepsis or infectious episodes in severely burned children. J Trauma 2006 (in review).
111. Pereira CT, **Jeschke MG**, Mlcak RP, Przkora R, Celis M, Lee JO, Sanford AP, Herndon DN. Longitudinal Assessment of Integra™ for Primary Burn Reconstruction: A Randomized Pediatric Clinical Trial. Crit Care Med 2006: (in review).
112. **Jeschke MG**, Herndon DN, Kulp G, Przkora R, Mlcak R, Finnerty CC. Combination of recombinant human growth hormone (*rhGH*) and Propranolol decreases hypermetabolism and inflammation in severely burned children. Ann Surg 2006 (in review).
113. Przkora R, Herndon DN, **Jeschke MG**. The factor age and the recovery of severely burned children. Pediatrics 2006 (in review).
114. **Jeschke MG**, Finnerty CC, Mlcak RP, Norbury W, Przkora R, Herndon B, Swick A, Herndon DN. Age differences in the inflammatory and hypermetabolic response post burn. Crit Care Med 2006 (in review).
115. Finnerty CC, Herndon DN, **Jeschke MG**. Inhalation injury in severely burned children does not augment the systemic inflammatory response. Crit Care 2006 (in review).
116. Norbury WB, Herndon DN, Chinkes D, **Jeschke MG**. Urine cortisol and catecholamines post-burn: Acute and long-term expression profile. JCEM 2006 (in review).

117. Herndon DN, Finnerty CC, **Jeschke MG**, Moldawer LL, López MC, Remick DG, Baker HV for the Inflammation and the Host Response to Injury Large-Scale Collaborative Research Program. Prolonged Alterations in Leukocyte Gene Expression Characterize the Human Response to Burn Injury in Children. Ann Surg 2006 (in review).
118. Przkora R, Herndon DN, Sanford AP, Lee JO, Meyer WJ, Chinkes DL, Mlcak RP, **Jeschke MG**. Persisting Effects of Extended Growth Hormone Therapy in Severely Burned Children are Dose-Related. JCEM 2006 (in review).
119. **Jeschke MG**, Pereira CT, Mlcak R, Barrow RE, Finnerty CC, Przkora R, Herndon DN. Gender differences in the postburn response: Does it make a difference? JCEM 2006, (in review).
120. **Jeschke MG**, Finnerty CC, Norbury W, Mlcak RP, Przkora R, Herndon DN. Burn size determines the inflammatory and hypermetabolic response. Am J Pathol 2006 (in review).
121. **Jeschke MG**, Klein D, Herndon DN, Thasler W, Bolder U, Schlitt HJ, Jauch KW, Weiss T. Insulin decreases inflammatory signal transcription factor expression in primary human hepatocytes after LPS challenge. J Hepatology 2006 (in review).
122. Branski LK, Herndon DN, Masters OE, Celis M, Norbury WB, **Jeschke MG**. Amnion in the treatment of pediatric partial-thickness facial burns. PRS 2006 (in review).
123. **Jeschke MG**, Finnerty CC, Norbury W, Branski LK, Kulp G, Mlcak RP, Herndon DN. The pathophysiologic response to severe burn injury. Crit Care Med 2006 (in review).

Books and Book chapters

1. Köveker G, **Jeschke M**, Hermanuz V, Coerper S, Becker HD. The influence of vascular graft materials upon vascular healing mechanisms. In: Chirurgisches Forum 1995 für experimentelle und klinische Forschung. Hrsg.: Hierholzer/Seifert/Hartel. Springer Verlag. 1995.
2. **Jeschke MG**. Inhalation Injury. In: Handbook of Burn Care. Editors: Herndon DN, Wolf SE. Vademecum, Landes Bioscience 1999; Pp: 90-96.
3. **Jeschke MG**, Barrow RE, Vita R, Jauch KW, Herndon DN. IGF-I/BP-3 wirkt antiapoptotisch auf Hepatozyten über eine Stimulation des Nitric Oxide und NF-kappa B Signal-Pathways. Chirurgisches Forum 2000; 19: 577-560.
4. **Jeschke MG**. Nomograms and useful information. Editors: Herndon DN, Barret JP. In: A Color Atlas of Burn Care. WB Saunders, Philadelphia 2000. Pp: 173-175.
5. **Jeschke MG**. Insulin-like growth factor-I plus insulin like growth factor binding protein-3 affects the hepatic acute phase response. In: The Year Book of Surgery. Editor: Copeland III EM. Mosby, St. Louis 2001; Pp: 222-225.
6. **Jeschke MG**. The hepatic response to a thermal injury. In: Total Burn Care. Editor: Herndon DN. Saunders, New York 2001; Pp 288-299.
7. **Jeschke MG**. Ernährung bei Verbrennungen. In: Ernährungsmedizin. Editor: Jauch KW. (in press).
8. **Jeschke MG**. Infektionen. In Tscherne Lehrbuch der Unfallchirurgie. Editor: Nerlich M, Berger A. Springer Verlag, Berlin, 2002: Pp 289-346.
9. Weigel B, **Jeschke MG**, Nerlich M. Weichteile und Weichteilinfektionen. In Praxisbuch Unfallchirurgie. Editor: Weigel B, Nerlich M. Springer Verlag, Berlin. 2004: Pp 964-1019.
10. Norbury W, **Jeschke MG**, Herndon DN. Metabolic Changes Following Major Burn Injury: How to improve outcome. Yearbook of Intensive Care and Emergency Medicine. Editor: JL Vincent. Springer Berlin 2006: Pp 514-525.
11. **Jeschke MG**. The hepatic response to a thermal injury. In: Total Burn Care. Editor: Herndon DN. Saunders, New York 2006, in press.
12. **Jeschke MG**. Hepatic response to a severe injury. Yearbook of Intensive Care and Emergency Medicine. Editor: JL Vincent. Springer Berlin 2007: in press.

Presentations/Abstracts (First Author)

National and International Presentations

1992
International surgical congress SSC, Lausanne, Switzerland.
German Society for Plastic and Reconstructive Surgery, Berlin, Germany.
1993
European Society for Vascular Surgery. Vienna, Austria.
1997
Immune consequences of shock, trauma and sepsis, Munich, Germany.
American Burn Association, New York, USA.
Experimental Biology (FASEB), New Orleans, USA.
International Symposium Advances in the therapy of burn children, Graz, Austria.
Association for Academic Surgery, Dallas, USA.
American College of Surgery, Committee on Trauma, Texas Chapter, Dallas, Texas.
1998
The Society of Critical Care Medicine, Frontiers in Critical Care, San Antonio, USA.
Residents competition American College of Surgery, San Antonio, USA.
American Burn Association, Chicago, USA.
American Gastroenterological Association, New Orleans, USA.
International Symposium on Regulatory Peptides, Mackinac Island, Michigan, USA.
Science Forum, Sealy Center for Molecular Science, Galveston, USA.
The American Association for the Surgery of Trauma, Baltimore, Maryland, USA.
American College of Surgery, Committee on Trauma, Texas Chapter, Houston, Texas.
Association for Academic Surgery. Seattle, Washington, USA.
Residents competition American College of Surgery, San Antonio, USA.
1999
American College of Surgery, Committee on Trauma, Washington, DC.
European Shock Society. Vienna, Austria.
American College of Surgery, Surgical Forum. San Francisco, CA.
Deutsche Gesellschaft für Handchirurgie. Hannover, Germany.
Bio Valley Tissue Engineering Symposium. Freiburg, Germany.
Deutsche Gesellschaft für Chirurgie. Berlin, Germany.
2000
World Congress on Trauma, Shock, Inflammation and Sepsis. Munich, Germany.
American Burn Association. Las Vegas, USA.
Deutschen Gesellschaft für Wundheilung und Wundbehandlung, Würzburg, Germany.
Tagung der Vereinigung der Bayerischen Chirurgen. Regensburg, Germany.
Wundheilung der Deutschen Gesellschaft für Chirurgie, Tübingen, Germany.
2001
American Burn Association. Boston, USA.
Deutsche Gesellschaft für Chirurgie.München, Germany.
Deutsche Gesellschaft für Wundheilung und Wundbehandlung, Ulm, Germany.
Bayerische Gesellschaft für Chirurgie. Otto-Götze-Preisträger Sitzung Murnau, Germany.
American College of Surgeons. New Orleans, USA.
Falk symposium. Hannover, Germany.
Bio Valley Tissue Engineering Symposium. Freiburg, Germany.
2002
European Surgical Association. Lissabon, Portugal.
SIS World Meeting. Madrid, Spain.

Deutsche Gesellschaft für Chirurgie, Berlin, Germany.
Deutschen Gesellschaft für Wundheilung/ Chirurgie, Hamburg, Germany.
European Shock Society. Oslo, Norway.
Chirurgische Forschungstage. Deutsche Gesellschaft für Chirurgie, Köln, Germany.
Arbeitsgemeinschaft für Wundheilung. Freiburg, Germany.
SIS-E, Como, Italy.

2003

Jahrestagung der Bayerischen Chirurgen, München, Germany.
Deutsche Gesellschaft für Wundheilung und Wundbehandlung, Augsburg, Germany.
European Tissue Repair Society, Amsterdam, Netherlands.
German Society of Plastic Surgery, Freiburg, Germany.
German College of Surgery, Chapter Surgical Research, Berlin, Germany.

2004

Society of Critical Care Medicine, Orlando, Florida.
World Congress on Trauma, Shock, Inflammation and Sepsis, Munich, Germany.
SIS-E, Cork, Ireland.
German College of Surgery, Berlin, Germany.
German Society of Trauma Surgery, Berlin, Germany.
Southern Surgical Association, Palm Beach, Florida, USA.
Association for Academic Surgery, Houston, Texas, USA.

2005

Society of Critical Care Medicine, Phoenix, Arizona.
Society University Surgeons, Nashville, Tennessee.
American Burn Association, Chiago, IL.
SIS and SIS-E, 25th Annual Meeting, Miami, Florida.
Shock Society, Marco Island, Florida.
AAST, Atlanta, Georgia.

2006

Society Critical Care Medicine, San Francisco, California.
Academic Surgical Congress (SUS and AAS), San Diego, California.
American Burn Association, Las Vegas, Nevada.
Wound Healing Society, Phoenix, Arizona.
SIS, La Jolla, California.
Shock, Brunswick, Colorado.
International Society for Burn Injuries (ISBI), Fortaleza, Brazil.
AAST, New Orleans, Louisiana.

2007

Society Critical Care Medicine, Orlando, Florida.
Academic Surgical Congress (SUS and AAS), Phoenix, Arizona.
American Burn Association, San Diego, California.

Invited Presentations

1. "Liposomal gene transfer in thermal injury". Baylor College of Medicine, Houston, Texas, USA. 1998
2. "Liposomes and gene transfer". Texas Somatomedin Club, UTMB, Galveston, Texas, USA. 1998.
3. "Recombinant human Growth Hormone (rhGH) treatment attenuates pro-inflammatory cytokines and acute phase proteins in pediatric burn patients." German Association for Enteral and Parenteral Nutrition, Regensburg, Germany. 1999.
4. "Insulin-like growth factor-I plus insulin-like growth factor binding protein-3 attenuates the pro-inflammatory acute phase response in severely burned children." European Shock Society, Vienna, Austria. 1999.

5. "New strategies for the treatment of chronic wounds: The use of gene therapy." Bayerischer Chirurgen Kongress. Regensburg, Germany. 2000.
6. "Wachstumsfaktoren und Gen-Therapie". Vorsitz und Vortrag 3. Regensburger Wundkongress. Regensburg, Germany. 2001.
7. „Möglichkeiten und Effektivität des KGF Gentransfers". Deutsche Gesellschaft für Wundheilung. 3rd Bio Valley Tissue Engineering Symposium. Freiburg, Germany (2001).
8. „Neue Therapiestrategien in der Wundheilung". 1 Regensburger Kongress Subathmosphärische Therapie bei Wundheilungsstörungen, Regensburg, Germany, 2001.
9. „Wachstumsfaktoren und Gentherapie bei chronischen Wunden". Kongress der Deutschen Gesellschaft für Wundheilung und Wundbehandlung. Hamburg, Germany, 2002.
10. „Physiologie und Pathogenese der Wundheilung". 3. Interdisziplinäres Regensburger Forum für Wund-Stoma und Inkontinenzmanagement, Regensburg, Germany (2002).
11. „Hepatic metabolic changes after trauma". 10th Congress of the European Shock Society. Oslo, Norway (2002).
12. "Mechanisms and possibilities of liposomal non-viral gene transfer". European Tissue Repair Society. Nice, France. (2002).
13. "Was tun wenn Wunden nicht heilen? Neuster Stand der Wundheilungsforschung". 10. Fortbildungsreihe Unfallchirurgie am Klinikum der Universität Regensburg.
14. „Intensivierte Insulintherapie bei Sepsis-Verbesserung der Überlebenschancen?" Symposium der Universitätskliniken des Saarlandes, Homburg/Saar, Germany (2003).
15. „Modern wound management". ECET Congress, München, Germany (2003).
16. „Gen Therapie: ein neuer Therapieansatz beim diabetischen Ulcus. Vor- und Nachteile". Deutsche Gesellschaft für Chirurgie, Deutscher Chirurgenkongress, CAW, München (2003).
17. „Modern wound management". ECET Congress, München, Germany (2003).
18. "Wachstumsfaktoren- Come back in Sicht?". 7 Kongress der Deutschen Gesellschaft für Wundheilung und Wundbehandlung (DGfW), Augsburg, Germany (2003).
19. „Gentherapie beim Ulcus cruris venosum". Jahrestagung der Deutschen Gesellschaft für Phlebologie, Nürnberg, Germany (2003).
20. „Insulintherapie für kritisch Kranke". Forum for Intensive care medicine and critical care medicine, Königswinter, Germany (2003).
21. „Effect of anabolic agents on the hepatic acute phase response". 6th World Congress on Trauma, Shock, Inflammation and Sepsis, Munich, Germany (2004).
22. "The use of locally administered growth factors to ameliorate the systemic catabolic response". 6th World Congress on Trauma, Shock, Inflammation and Sepsis, Munich, Germany (2004).
23. "Biotechnologische Modulation der Wundheilung: Wunschtrauma oder realistische Erwartung?". 45. Österreichischer Chirurgenkongress. Klagenfurt, Österreich (2004).
24. „The effect of insulin on the systemic inflammatory response during hypermetabolism". European Shock Society, Vienna, Austria (2005).
25. "The effect of insulin on postburn hypermetabolism." Mass General Hospital and Shriners Hospital for Children, Boston, MA (2006).
26. "Genomic, proteomic, and mitochondrial changes post burn." European Shock Society, Ulm, Germany (2006).
27. "The effect of rhGH after trauma". American Heart Association, Chicago, USA (2006).

Editorial Board

Burns
Cancer Therapy, Gene Therapy

Invited Peer for Journals

American Journal of Physiology
Annals of Surgery
Archives of Surgery
British Medical Journal
Critical Care Medicine
Experimental Biology and Medicine
Gastroenterology
Gene Therapy
Gut
Hepatology
Human Gene Therapy
Journal of Burn Care and Research
Journal of Hepatology
Journal of Investigative Dermatology
Molecular Therapy
Shock
Wound Repair and Regeneration